MR# 337573

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Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of a Repeated Dose Toxicity Study in Mice with [ ] (CAS No.[ ])

Dear Sir/Madam:

[ ] is submitting results of a Repeated Dose Toxicity Study in C57BL/6 J Rj Mice, administration via drinking water for 4 weeks with [ ] (CAS No.[ ]) conducted by [ ]. The substance is an experimental herbicide.

The aim of the study is to assess the toxicological profile of the test substance including the target organs and the "no observed adverse effect level" (NOAEL) after 4-week administration via the drinking water according to the following guidelines:

- OECD Guidelines for Testing of Chemicals; Method No. 407: Repeated Dose 28-day Oral Toxicity Study in Rodents; adopted 03 Oct 2008.
- Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Part B: Methods for the determination of toxicity and other health effects:
  B.7. Repeated Dose (28 Days) Toxicity (Oral); Official Journal of the European Union, No. L 142.

The test substance was administered to groups of 15 male and 15 female C57BL/6 J Rj mice for 4 weeks. The nominal dose levels were 700, 2000 and 6000 ppm via the drinking water. At the end, all animals were sacrificed and clinical pathology as well as pathology parameters were examined.

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The following is a summary of the most relevant results:

6000 ppm:

- Significantly decreased water consumption in males up to -43% between day 18 to 21
- Significantly decreased water consumption in females up to -52% between day 18 to 21
- Significantly decreased body weights (-13%) on day 21 in females
- Significantly decreased body weight changes in males up to -153% between day 0 and 7
- Significantly decreased absolute testes weights (-19%)
- Decreased (not significantly) absolute seminal vesicle weights (-12%)
- Decreased (not significantly) absolute adrenal glands weights in females (-18%)
- Significantly increased relative kidney weights in males (+15%)
- Significantly increased relative liver weights in males (+14%)
- Decreased (not significantly) relative seminal vesicle weights (-9%)
- Decreased (not significantly) relative testes weights (-15%)
- Centrilobular liver hypertrophy in 5 of 5 males and 3 of 5 females
- Lymphoid liver infiltration in 4 of 5 males and 2 of 5 females
- Tubular degeneration in testes in 5 of 5 males
- Intratubular multinuclear cells in testes in 5 of 5 males

2000 ppm:

- Significantly decreased water consumption in males up to -24% between day 4 to 7
- Significantly decreased water consumption in females up to -23% between day 4 to 7
- Decreased (not significantly) absolute testes weights (-5%)
- Significantly increased relative liver weights in males (+14%)
- Decreased (not significantly) relative seminal vesicle weights (-5%)
- Centrilobular liver hypertrophy in 5 of 5 males and 5 of 5 females
- Tubular degeneration in testes in 3 of 5 males
- Intratubular multinuclear cells in testes in 2 of 5 males

700 ppm:

- Significantly decreased water consumption (-19%) in females between day 25 to 28
- Significantly increased relative liver weights in males (+7%)
- Tubular degeneration in testes in 2 of 5 males

[[redacted]] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures